# PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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MELBOURNE VIC 3000

# PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Rule 71.1)

Date of mailing *(day/month/year)* 06 JUL 2004

Applicant's or agent's file reference
0351025373

IMPORTANT NOTIFICATION

| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
|---|---|---|
| PCT/AU2004/000490 | 14 April 2004 | 15 April 2003 |

Applicant

VITAL HEALTH SCIENCES PTY LTD et al

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translations to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the *PCT Applicant's Guide*.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed invention is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the IPEA/AU

AUSTRALIAN PATENT OFFICE
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Authorized officer

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# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

| Applicant's or agent's file reference | FOR FURTHER ACTION | See Form PCT/IPEA/416 |
|---|---|---|
| 0351025373 | | |
| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
| PCT/AU2004/000490 | 14 April 2004 | 15 April 2003 |

International Patent Classification (IPC) or national classification and IPC

Int. Cl.[7] C07F 9/09, 9/10, 9/12, 9/117, A61K 9/08, 31/661, 31/6615, 31/683, 31/685, A61P 9/00, 23/00, 25/24

Applicant

VITAL HEALTH SCIENCES PTY LTD et al

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

a. ☐ *(sent to the applicant and to the International Bureau)* a total of · sheets, as follows:

☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- ☐ Box No. I Basis of the report
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

| Date of submission of the demand | Date of completion of the report |
|---|---|
| 18 June 2004 | 30 June 2004 |
| Name and mailing address of the IPEA/AU | Authorized Officer |
| AUSTRALIAN PATENT OFFICE<br>PO BOX 200, WODEN, ACT 2606, AUSTRALIA | S.D. IDRIS |

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/AU2004/000490

**Box No. I Basis of the report**

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3 and 23.1 (b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

☒ the international application as originally filed/furnished

☐ the description:

pages as originally filed/furnished
pages* received by this Authority on with the letter of
pages* received by this Authority on with the letter of

☐ the claims:

pages as originally filed/furnished
pages* as amended (together with any statement) under Article 19
pages* received by this Authority on with the letter of
pages* received by this Authority on with the letter of

☐ the drawings:

pages as originally filed/furnished
pages* received by this Authority on with the letter of
pages* received by this Authority on with the letter of

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages
☐ the claims, Nos.
☐ the drawings, sheets/figs
☐ the sequence listing (*specify*):
☐ any table(s) related to the sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages
☐ the claims, Nos.
☐ the drawings, sheets/figs
☐ the sequence listing (*specify*):
☐ any table(s) related to the sequence listing (*specify*):

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/AU2004/000490

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Claims | 1-16 | YES |
| | Claims | | NO |
| Inventive step (IS) | Claims | 1-16 | YES |
| | Claims | | NO |
| Industrial applicability (IA) | Claims | 1-16 | YES |
| | Claims | | NO |

2. Citations and explanations (Rule 70.7)

The International Search Report identified the following citations:

**D1)** AU 43870/00

**D2)** Derwent Abstract Accession No. 26921 K/11

**D3)** Derwent Abstract Accession No.1981-89192D/48

**D4)** GB 1,121,683

**D5)** STN File CA, Abstract 139:399976

**D6)** WO 2001/046204

**D7)** GB 2 227 662

Citations **D1-D5** are the most relevant.

None of the citations teaches or fairly suggests the preparation of phosphorylated derivatives of pravastatin, atorvastatin, venlafaxine or mixtures thereof.

Accordingly, Claims 1-4, 6, 13, 14 and their dependent claims 15-16 are novel and involve inventive step in light of the citations.

Claims 5 and 12 relate to a process for phosphorylating secondary alcohols and the product of that process wherein the process involves reacting the secondary alcohol with $P_4O_{10}$ in the presence of an alkali salt of a fatty acid. The problem faced by the inventor of the present application is to overcome the disadvantage associated with previous methods used to phosphorylate secondary alcohols, namely that of a significant degree of dehydration of the secondary alcohol to form a double bond (page 4 lines 13-15). And the inventor proffered the solution of the use of an alkali metal salt of a free fatty acid. Suitable alkali metal salts of fatty acids include the sodium and potassium salts of oleic or valeric acid.

None of **D1** to **D5** discloses the use of an alkali metal salt of a fatty acid.

Accordingly, Claims 5 and 12 and their dependent claims are novel and involve inventive step in the light of **D1** to **D5**.

The phosphate and phosphate complex derivatives of the invention are pharmaceuticals with improved

[illegible] subject matter has industrial applicability.